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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,046	08/25/2003	David B. Fick	14377.110	3231
45200	7590	09/28/2005	EXAMINER	
PRESTON GATES & ELLIS LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319			RAO, DEEPAK R	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/648,046

Applicant(s)

FICK ET AL.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 ~~is~~/are pending in the application.
- 4a) Of the above claim(s) 3-19, 21, 23-30, 33-37, 40, 41, 43-46, 49-58 and 61-71 ~~is~~/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 20, 22, 31, 32, 38, 39, 42, 47, 48, 59 and 60 ~~is~~/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09262003</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-71 are pending in this application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-71, drawn to compounds of structure as disclosed in claim 1 wherein A is represented by formula (I) wherein A5 is carbon (i.e., 1,3-diazine compounds), classified in class 544, subclass 242+.
- II. Claims 1 and 31-59, drawn to compounds of structure as disclosed in claim 1 wherein A is represented by formula (I) wherein A5 is nitrogen (i.e., 1,3,5-triazine compounds), classified in class 544, subclass 180+.

The inventions are distinct, each from the other because of the following reasons:

Groups I-II are drawn to structurally dissimilar compounds. They are made independently and used independently. They would be expected to raise different issues of patentability if a compound of Group I, consisting of 1,3-diazinyl compounds were anticipated, the anticipatory reference would not necessarily render obvious the compounds of Group II or vice-versa. They are not art recognized equivalents, they are classified separately and require separate searches in the literature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Further, **along with the election of a single group from above, election of a single species that falls within that group is also required.** Claims are generic to a plurality of disclosed patentably distinct species comprising the species disclosed in the examples. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Louis Cullman on September 21, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-71 and the species of Example 1 (page 19, lines 21-22). Affirmation of this election must be made by applicant in replying to this Office action. Claims 1 and 31-59 (**all in part**, wherein A is a heterocyclic moiety of formula (I) wherein A₅ is N) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

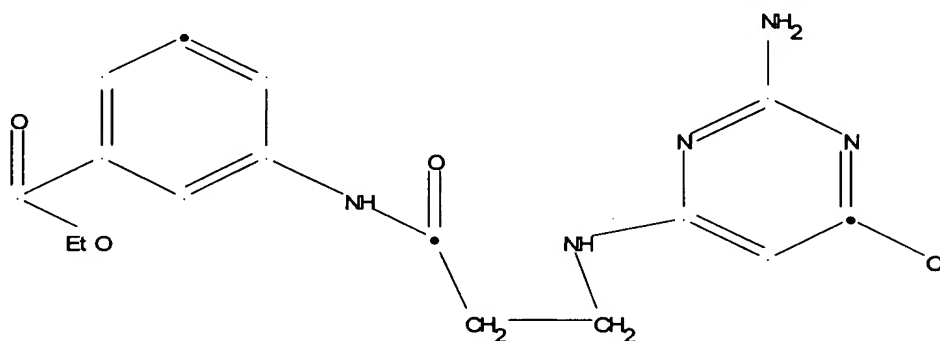
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant's election of the species of Example 1 (compound of claim 60) is acknowledged. The species is depicted below for convenience:



The guidelines in MPEP § 803.02 provide that upon examination if prior art is found for the elected species, the examination will be limited to the elected species.

Content of MPEP § 803.02 is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, **a second action on the merits on the elected claims would be final.**

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. **The prior art search, however, will not be extended unnecessarily to cover all nonelected species.** Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

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The elected species was found in the prior art search. Claims 1, 2, 20, 22, 31, 32, 38, 39, 42, 47, 48, 59 and 60 read on the elected species. As per the guidelines of MPEP § 803.02, the Markush-type claims were examined to the extent readable on the elected species. The non elected species and the generic subject matter drawn to the non elected species is withdrawn from further consideration. Accordingly, claims 3-19, 21, 23-30, 33-37, 40-41, 43-46, 49-58 and 61-71 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 20, 22, 31, 32, 38, 39, 42, 47, 48, 59 and 60 are rejected under 35

U.S.C. 112, first paragraph, because the specification, while being enabling for a pyrimidine compounds and salts thereof represented by the schematic structure (as depicted in claim 1), does not reasonably provide enablement for all other types of “derivatives or analogues” thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art,

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4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The instant claim recites “A pyrimidine derivative or analogue” wherein there is insufficient description in the specification regarding the types of 'derivatives' and 'analogues' intended by the recitation. The specification at page 77 explains that ‘salts and prodrug esters fall within the scope of pyrimidine derivatives and analogues’ and further provides that ‘prodrug esters can be formed by reaction of either a carboxyl or hydroxyl group with either an acid or an alcohol to form an ester’. However, the definition of various substituent groups in formula (I) already include such groups, i.e., acids as well as esters, see e.g., the term “OZ” wherein Z is H, alkyl, etc. The specification does not provide what other 'compounds' of the invention are intended to be the above referred “derivatives and analogues”. As explained herein, the generic formula of the claims already include both esters and the corresponding free acid forms. There is no disclosure regarding any other types of esters etc. that are capable of providing compounds of the invention. Further, specification does not provide sufficient description of the term “prodrug” with supporting disclosure and examples. A prodrug is any compound which is converted in to the pharmaceutically active compound by hydrolysis *in vivo* and the specification, however, does not provide any disclosure of what these compounds might be that *in vivo* transform in to the instantly claimed compounds. The specification does not provide what other 'compounds' of the invention are intended to be “derivatives and analogues”. Since

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functional groups such as esters, amides, etc. are already included in the claimed compounds, it is not clear whether compounds bearing these groups are excluded from being a potential “pharmaceutically acceptable derivatives” of the claimed invention. If compounds bearing these groups (i.e., ester, etc.), which are likely to undergo *in vivo* transformation, are excluded then what is included in the definition of the above term and where on the structural formula (I) are these groups placed; the specification does not provide any direction to one of ordinary skill in the art.

It is suggested that the recitation “A pyrimidine derivative or analogue” be replaced with -- A compound or a salt thereof -- in all occurrences, throughout the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 20, 22, 31, 32, 38, 39, 42, 47, 48, 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite “**pyrimidine derivative or analogue**” in line 1 of each of the claim (all occurrences). This is confusing because the heterocyclic moiety represented by A} can be a 1,3-diazine (i.e., pyrimidine) or 1,3,5-triazine (withdrawn from consideration), therefore, the structure in the claim is not drawn only to ‘pyrimidine’ compounds. Further, the structure includes dihydro- or tetrahydropyrimidine compounds as well. Further, the recitation ‘derivative or analogue’ is open ended. These terms would allow for groups other than those

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recited in the claim. Replacing the above recitation with -- **compound** -- (all occurrences) is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 2, 20, 22, 31, 32, 38, 39, 42, 47, 48, 59 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Diamond et al., U.S. Patent No. 6,630,478 (which corresponds to S.No. 09/899,901 having effective filing date of July 7, 2000). The reference identically discloses the instantly elected species, see col. 16, lines 61-62.

2. Claims 1, 2, 20, 22, 31, 32, 38, 39, 42, 47, 48, 59 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Glasky et al., U.S. Publication No. 2002/0040031 (which corresponds to S.No. 09/899,611 having effective filing date of July 7, 2000). The reference identically discloses the instantly elected species, see page 9, paragraph [0128], the first species.

The applied references have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

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inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Duplicate Claims

Applicant is advised that should claim 1 be found allowable, claim 59 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 59 only recites a characteristic or property of the compound and does not further limit claim 1.

Receipt is acknowledged of the Information Disclosure Statements filed on September 26, 2003 and a copies is enclosed here with.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Acting-SPE of 1624, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deepak Rao
Primary Examiner
Art Unit 1624

September 25, 2005